OCT 0 8 2002

510(k) Summary
IRIDEX® Corporation K022227
Family of IRIS Medical® EndoProbe® Handpieces

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, CA 94043

Contact Person: John D'Angelo
(650) 962-8848 ext. 3905

Date Prepared: July 9, 2002

Device Information

Trade Name:	Family of IRIS Medical EndoProbe Handpieces
Classification Name:	Laser, Ophthalmic, Accessory
CFR Section:	886.4390
Product Code:	HQF

Predicate Devices

The family of IRIS Medical EndoProbe handpieces is substantially equivalent in intended use and/or method of operation to other currently legally marketed laser probes including IRIDEX Corporation's IRIS Medical EndoProbe (K020374), the Alcon Endolaser Probes (K962592), the HGM Illuminating and Aspirating Probes (K931784 and K925663), the STI Aspirating Endo Ocular Probe with Illumination (K921488), and the Infinitech Aspirating Laser Probe (K946135).

Device Description

The family of IRIS Medical EndoProbe handpieces is comprised of the following main components: a universal SMA style input connector, a glass fiber optic protected by a PVC (vinyl) jacket, a handle, and a medical grade stainless steel needle. The Illuminating EndoProbe has an additional illumination fiber optic with jacket.

Intended Use

The family of IRIS Medical EndoProbe handpieces is intended for use in performing ophthalmic laser treatments to deliver laser energy to the treatment area inside the eye, the aspiration function is indicated for use when unwanted fluid is present in the eye causing refraction or scattering of the laser beam from the intended treatment site, and the illumination function is indicated for use to illuminate the interior of the eye. The handpieces are offered in straight or angled styles, and with a universal SMA connector that allows the family of EndoProbe handpieces to be used with compatible laser systems, such as IRIS Medical and Lumenis. The handpieces are cleared for use for the particular indications of the laser system to which they are attached.

Conclusion

The family of IRIS Medical EndoProbe handpieces shares similar indications for use, materials, and similar performance characteristics as, and thus is substantially equivalent to, the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2002

Mr. John D'Angelo
Vice President, Regulatory Affairs
and Quality Assurance
IRIDEX Corporation
1212 Terra Bella Avenue
Mountain View, California 94043

Re: K022228
Trade/Device Name: Family of IRIS Medical EndoProbe Handpieces
Regulation Number: 886.4390
Regulation Name: Opthalmic Laser
Regulatory Class: II
Product Code: GEX
Dated: July 9, 2002
Received: July 10, 2002

Dear Mr. D'Angelo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): ~~Pending~~ K022228

Device Name: Family of IRIS Medical® EndoProbe® Handpieces

Indications For Use:

The family of IRIS Medical EndoProbe handpieces is intended for use in performing ophthalmic laser treatments to deliver laser energy to the treatment area inside the eye, the aspiration function is indicated for use when unwanted fluid is present in the eye causing refraction or scattering of the laser beam from the intended treatment site, and the illumination function is indicated for use to illuminate the interior of the eye. The handpieces are offered in straight or angled styles, and with a universal SMA connector that allows the family of EndoProbe handpieces to be used with compatible laser systems, such as IRIS Medical and Lumenis. The handpieces are cleared for use for the particular indications of the laser system to which they are attached.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K022228

Prescription Use ✓ OR (Per 21 CFR 801.109) Over-The-Counter Use _____